

CBER Computer Assisted License Application (CALA) Questionnaire

Date: December 1, 1999

Subject: Anticipated **BLA/CALA** submission to CBER

QUESTION	RESPONSE
1. What is the planned target date for the submission of your BLA/CALA?	BLA: CALA:
2. Will the submission comply with CBER's current guidances?	
3. What information will be provided electronically? On paper? a) Complete BLA text? b) Clinical datasets & codes (SAS)? c) Case Report Forms (CRFs)? d) Case Report Tabulations (CRTs)? e) Other? (i.e., images,)	a) b) c) d) e)
4. Total number of patients in study? (ballpark estimate). Anticipated number of patients for which you will submit CRF's as an e-doc.	
5. What is the total size, in gigabytes, of the electronic submission.	
6. Will an electronic table's of contents be provided (main TOC and item TOC's)?	
7. When will a CDrom containing a demo of your CALA be provided (atleast 4 months prior to the submission date)?	
8. Will the applicant provide reviewer training in the use of the CALA, no more than 2 weeks after the submission of the BLA/CALA? Will the applicant provide a quick reference manual to aid the review team in the use of the electronic submission.	

QUESTION	RESPONSE
9. Will scientific and technical support be provided once the review has started, if the reviewer has questions or problems with the CALA?	

Outstanding Sponsor Issues/Questions: